

Docket No.: 20022/42179  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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In re Patent Application of:  
Umberto Benatti et al.

Application No.: 10/584,874

Confirmation No.: 7927

Filed: June 7, 2007

Art Unit: 1614

For: Glutathione Derivatives and Their Uses for the  
Treatment of Viral Diseases

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Examiner: Ronald T. Niebauer

**RESPONSE TO RESTRICTION REQUIREMENT**

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In the Office Action dated December 8, 2005, applicants are required to elect one of the following groups of claims:

Group 1, claims 15-18, 23, drawn to glutathione derivatives, compositions of glutathione derivatives.

Group 2, claims 19, 25, drawn to a method of treating a disease caused by a paramyxovirus.

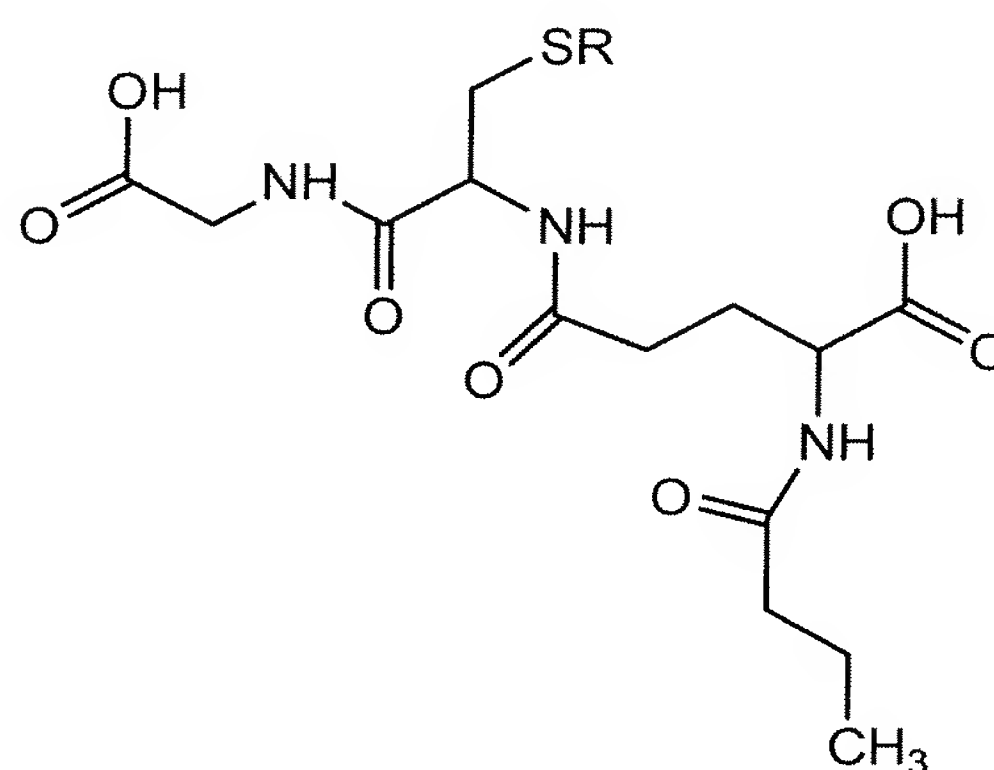
Group 3, claims 20, 26, drawn to a method of treating a disease caused by a orthomyxovirus.

Group 4, claims 21, 27, drawn to a method of treating a disease caused by Herpes Simplex-1.

Group 5, claims 22, 28, drawn to a method of treating a disease caused by HIV.

Applicants hereby elect the claims of examiner's Group I, namely, claims 15 through 18, inclusive, and claim 23, with traverse, for examination on the merits at this time.

Applicants wish to point out an inadvertent error in the structure of claim 15, and thereby clarify the intended structure. In particular, the structure of claim 15 properly should be the structure set forth in Figure 1, i.e.,



This structure is supported by the structure of Figure 1. Applicants apologize for this inadvertent error and will correct the specification and claims in a response to a first action on the merits.

It is submitted that all claims 15 through 28 should be examined at this time. According to PCT Rule 13, claims of different categories with common special technical features do *not* lack unity. Also, see Example 1 in PCT Gazette, page 52, Part 2 I. (copy enclosed).

In the present invention, the common special technical feature in *all* claims is the novel glutathione derivatives recited in claim 15, for example. There may be a lack of unity only if this common technical feature lacks novelty or is obvious. See PCT Gazette page 49, part 1(a), (copy enclosed).

The examiner relies upon Anderson et al. U.S. Patent No. 5,464,825 for disclosing glutathione derivatives wherein R1 can be propyl, which would result in an n-butanoyl group, thus contending that the technical features of the present claims do not provide a contribution over the prior art and lack unity. Applicants traverse this contention.

In particular, U.S. Patent No. 5,464,825 discloses glutathione derivatives at column 4, line 10. It is important to note that the reference is based on preparation and use of N-acyl glutathione monoalkyl esters (see, Abstract and column 3, line 65, for example). The difference between the presently claimed glutathione derivatives and those of the Anderson et al. reference is evident in the structure of column 4 and in the description of the patentees. Anderson et al. used derivatives "in which only the glycine carboxyl group is esterified" (column 4, lines 6-7), whereas according to the present claims, i.e., in the butanoyl –GSH of claim 15, the glycine residue must have a free carboxyl group. In other terms, claim 15 is directed to acid derivatives wherein the Anderson et al. patent is directed to monoesters.

Unity of invention in the present application is evidenced further by the International Search Report. In particular, *all* claims were searched. The standards regarding unity of invention that apply to the International Searching Authority *also* apply to the U.S. Patent Office with respect to this application. Therefore, the unity of invention requirement is fulfilled, and any reliance upon independence or distinctness of the invention is not relevant under the PCT.

In addition, M.P.E.P. §1893.03(d) provides that when making a lack of unity of invention requirement, the examiner *must* "explain why each group lacks unity with each other group (i.e., why there is no single general inventive concept) specifically describing the unique special technical feature in each group." A group of inventions is considered linked as to form a single general inventive concept when a technical relationship exists among the inventions that involves at least one common or corresponding special technical feature. That common special technical feature is present in *all* of claims 15-28.

The examiner has not provided *proper* reasons why each group lacks unity with each other group specifically describing the unique special technical feature in each group as required in M.P.E.P. §1893.03(d). The examiner has considered the type of claims,

e.g., compound, composition, and method of use, without considering the special technical features recited in, and common to, each claim, as set forth above. Furthermore, it must be noted that the claims of examiner's Groups 2-5, i.e., claims 19-22 and 24-28, *depend* from claim 15, and therefore *must* share a common technical feature with the claims of examiner's Group I.

The Office Action fails to indicate whether Groups 1-5 are classified in different classes or subclasses, but, even if differently classified, the inventions are not independent for the reasons set forth above *and* because the methods set forth in claims 19-22 and 24-28, and the compounds and compositions set forth in claims 15-18 and 23, are so closely related that a search for applicants' compound claims would necessarily encompass a search for applicants' method claims, and vice versa.

Therefore, even if unity of invention arguably is lacking, no evidence exists that a search and examination directed to all claims would be a *serious burden* on the examiner, as is required by M.P.E.P. §803. ("If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions." and "There must be a serious burden on the examiner if restriction is not required.")

Because search and examination of the entire application can be made without serious burden on the examiner, it would be wasteful of the time, effort, and resources of both the applicants and the Patent Office to prosecute the compound and method claims in separate applications. Search and examination of all groups of claims in a single application would be much more efficient than requiring the Patent Office to prosecute the compound and method claims in separate applications. Search and examination of all groups of claims in a single application would be much more efficient than requiring the Patent Office and applicants to do so in separate applications. Accordingly, it is submitted that all claims should be examined at this time.

The examiner also has issued an election of species requirement. In response applicants elect, with traverse, the glutathione derivatives wherein the thiol protection group R is H (see claim 16). It is submitted, however, that the examiner should expand the election

to include at least acetyl in addition to H. Applicants traverse the election requirement for the same reasons set forth above with respect to the traversal of the restriction requirement, and particularly, there is no undue burden on the examiner to search for the elected compound, i.e., R=H, and expand the search to other thio protecting R groups, e.g., acetyl. It is submitted that in searching for a compound when R=H, compounds wherein R is acetyl would necessarily be included in the search, and vice versa.

Claims readable on the elected species are elected claims 15-18 and 23, and non-elected claims 19-22 and 24-26.

Reconsideration and withdrawal of the restriction and election requirement are respectfully requested. An early action of the merits on all claims and species is solicited.

Dated: March 12, 2008

Respectfully submitted,

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S-03/2001 (E)  
30 August 2001

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## ANNEX B UNITY OF INVENTION

### Part 1

#### Instructions Concerning Unity of Invention

(a) **Unity of invention.** Rule 13.1 deals with the requirement of unity of invention and states the principle that an international application should relate to only one invention or, if there is more than one invention, that the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single general inventive concept.

(b) **Technical Relationship.** Rule 13.2 defines the method for determining whether the requirement of unity of invention is satisfied in respect of a group of inventions claimed in an international application. Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding "special technical features." The expression "special technical features" is defined in Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description and drawings (if any).

(c) **Independent and Dependent Claims.** Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression "category of claim" referring to the classification of claims according to the subject matter of the invention claimed—for example, product, process, use or apparatus or means, etc.).

(i) If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention. Equally, no problem arises in the case of a genus/species situation where the genus claim avoids the prior art. Moreover, no problem arises in the case of a combination/subcombination situation where the subcombination claim avoids the prior art and the combination claim includes all the features of the subcombination.

(ii) If, however, an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on that claim needs to be carefully considered. If there is no link remaining, an objection of lack of unity *a posteriori* (that is, arising only after assessment of the prior art) may be raised. Similar considerations apply in the case of a genus/species or combination/subcombination situation.

(iii) This method for determining whether unity of invention exists is intended to be applied even before the commencement of the international search. Where a search of the prior art is made, an initial determination of unity of invention, based on the assumption that the claims avoid the prior art, may be reconsidered on the basis of the results of the search of the prior art.

(d) **Illustrations of Particular Situations.** There are three particular situations for which the method for determining unity of invention contained in Rule 13.2 is explained in greater detail:

- (i) combinations of different categories of claims;
- (ii) so-called "Markush practice"; and
- (iii) intermediate and final products.

Principles for the interpretation of the method contained in Rule 13.2, in the context of each of those situations are set out below. It is understood that the principles set out below are, in all instances, interpretations of and not exceptions to the requirements of Rule 13.2.

Examples to assist in understanding the interpretation on the three areas of special concern referred to in the preceding paragraph are set out below.

(j) Rule 13.3 is not intended to constitute an encouragement to the use of alternatives within a single claim, but is intended to clarify that the criterion for the determination of unity of invention (namely, the method contained in Rule 13.2) remains the same regardless of the form of claim used.

(k) Rule 13.3 does not prevent an International Searching or Preliminary Examining Authority or an Office from objecting to alternatives being contained within a single claim on the basis of considerations such as clarity, the conciseness of claims or the claims fee system applicable in that Authority or Office.

## Part 2 Examples Concerning Unity of Invention

The application of the principles of unity of invention is illustrated by the following examples for guidance in particular cases.

### I. Claims in Different Categories

#### *Example 1*

Claim 1: A method of manufacturing chemical substance X.

Claim 2: Substance X.

Claim 3: The use of substance X as an insecticide.

Unity exists between claims 1, 2 and 3. The special technical feature common to all the claims is substance X.

#### *Example 2*

Claim 1: A process of manufacture comprising steps A and B.

Claim 2: Apparatus specifically designed for carrying out step A.

Claim 3: Apparatus specifically designed for carrying out step B.

Unity exists between claims 1 and 2 or between claims 1 and 3. There is no unity between claims 2 and 3 since there exists no common special technical feature between the two claims.

#### *Example 3*

Claim 1: A process for painting an article in which the paint contains a new rust inhibiting substance X including the steps of atomizing the paint using compressed air, electrostatically charging the atomized paint using a novel electrode arrangement A and directing the paint to the article.

Claim 2: A paint containing substance X.

Claim 3: An apparatus including electrode arrangement A.

Unity exists between claims 1 and 2 where the common special technical feature is the paint containing substance X or between claims 1 and 3 where the common special technical feature is the electrode arrangement A.

However, unity is lacking between claims 2 and 3 since there exists no common special technical feature between them.